4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2002-N-0153] (formerly Docket No. 2002N-0277)

RIN 0910-AG73

Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on establishment, maintenance, and availability of records. FDA is issuing this interim final rule (IFR) to amend FDA's regulation on the record availability requirements to implement the amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) made by the FDA Food Safety Modernization Act (FSMA). The FSMA amendment expands FDA's former records access authority beyond records relating to the specific suspect article of food to records relating to any other article of food that the Secretary of Health and Human Services (the Secretary) reasonably believes is likely to be affected in a similar manner. In addition, the FSMA amendment permits FDA to access records relating to articles of food for which the Secretary believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. This expanded records access authority will further help improve FDA's ability to

respond to, and further contain threats of serious adverse health consequences or death to humans or animals.

DATES: Effective date: This interim final rule is effective [INSERT DATE 7 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Comment date: Interested persons may submit either electronic or written comments on this interim final rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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ADDRESSES: You may submit comments, identified by Docket No. FDA-2002-N-0153 (formerly Docket No. 2002N-0277) and/or Regulatory Information Number (RIN) 0910-AG73 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, docket number and RIN for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legal Background

Each year about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die from food borne diseases, according to recent data from the Centers for Disease Control and Prevention (CDC) (Estimates of Foodborne Illness in the United States--CDC 2011 Estimates, available at http://www.cdc.gov/foodborneburden). This is a significant public health burden that is largely preventable.

FSMA (Public Law 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities to help it achieve higher rates of compliance with prevention and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to better ensure the safety of imported foods and directs FDA to build an integrated national food safety system in partnership with State and local authorities.

Section 101 of FSMA amends section 414(a) of the FD&C Act (21 U.S.C. 350c(a)). Section 414 was added to the FD&C Act by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188). As amended section 414(a) of the FD&C Act expands FDA's access to records. Specifically, FDA's access to records was expanded beyond records relating to the specific suspect article of food to records relating to any other article of food that the Secretary (by delegation FDA) reasonably believes is likely to be affected in a similar manner. In addition, FDA can now access records if FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. Decisions regarding whether FDA "reasonably believes" a food is affected in a similar manner to cause serious adverse health consequences or death to humans or animals would be made on a case-by-case basis because such decisions are fact-specific. Section 414(a) of the FD&C Act further provides that, at the request of an officer or employee duly designated by FDA, each

person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall permit such officer or employee to have access to and copy all records relating to such article and any other article of food that FDA reasonably believes is likely to be affected in a similar manner. FDA shall have access to the records that are needed to assist FDA in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals. To gain access to these records, the officer or employee must present appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner. The Bioterrorism Act also amended section 704(a)(1)(B) of the FD&C Act (21 U.S.C. 374(a)(1)(B)) to include a cross-reference to section 414 of the FD&C Act. Section 101 of FSMA amends this section by updating the cross-reference to refer to the amended version of section 414(a).

The amendments made by section 101 of FSMA to the FD&C Act were effective upon enactment of the law (January 4, 2011).

B. Brief History of Establishment, Maintenance, and Availability of Records

Among other things, section 306(a) of the Bioterrorism Act amended the FD&C Act by adding section 414(a) to the FD&C Act, which provided FDA with the authority to access records if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, persons who manufacture, process, pack, distribute, receive, hold, or import food must provide access to records related to the food that are needed to assist FDA in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or

animals. The statute provided for such records to be provided under certain conditions, including at reasonable times.

In addition, section 306(a) of the Bioterrorism Act added a new section 414(b) to the FD&C Act that provided, in part, that FDA may by regulation establish requirements regarding establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that are required to be kept by these regulations are those needed by FDA for inspection to allow FDA to identify the immediate previous sources and immediate subsequent recipients of food.

Section 306(b) of the Bioterrorism Act also amended section 704(a) of the FD&C Act to authorize FDA inspections of all records and other information described in section 414 of the FD&C Act, when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Further, section 306(c) of the Bioterrorism Act amended section 301 of the FD&C Act (21 U.S.C. 331) to make it a prohibited act to refuse to permit access to, or copying of, any record as required by section 414 or 704(a) of the FD&C Act; or to fail to establish or maintain any record as required by section 414(b) of the FD&C Act; or to refuse to permit access to, or verification or copying of, any such required record; or for any person to use to his own advantage, or to reveal, other than to FDA or officers or employees of the Department of Health and Human Services, or to the courts when relevant in any judicial proceeding under the FD&C Act, any information acquired under authority of section 414 of the FD&C Act.

In accordance with the Bioterrorism Act, FDA issued a proposed rule in the Federal Register on May 9, 2003 (68 FR 25188) (the 2003 proposed rule), proposing to require the

establishment and maintenance of records to identify the immediate previous sources and immediate subsequent recipients of food and the record availability requirements. On December 9, 2004, FDA issued a final rule in the Federal Register (69 FR 71562) (the 2004 final rule) specifying the requirements for the establishment and maintenance of records, including among other provisions the record availability requirements. The establishment, maintenance, and availability of records regulations have been codified at part 1, subpart J (21 CFR part 1, subpart J).

The current regulation at § 1.361 primarily tracks the language of section 414(a) of the FD&C Act prior to the amendments made by FSMA. However, the regulation does specify the timeframe in which the records must be provided in that requested records and information must be made available as soon as possible, not to exceed 24 hours, from the time of receipt of an official request. As specified by the statute, the request must be from an officer or employee designated by the Secretary who presents appropriate credentials and a written notice.

This IFR amends § 1.361 by replacing the current text with language that reflects the language of section 414 of the FD&C Act as amended by section 101 of FSMA. This amendment conforms the regulation to the statute that is now in effect. Upon publication of this IFR, records requested by FDA under amended section 414(a)(1) and (a)(2) of the FD&C Act will fall within the scope of the availability requirements in the regulation.

C. Justification for Interim Final Rulemaking

In accordance with the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(3)(B) and FDA's administrative practices and procedures regulations at § 10.40(e)(1) (21 CFR 10.40(e)(1)), FDA finds for good cause that use of prior notice and comment procedures for issuing this IFR is contrary to the public interest. This IFR modifies § 1.361 to be consistent

with the current statutory language in section 414(a) of the FD&C Act and to require that records and other information be provided as soon as possible, but no later than 24 hours from the receipt of an official records request. Because FDA's expanded records access authority was effective upon the enactment of FSMA, it is contrary to the public interest to require those members of the public whose records are requested under FDA's expanded authority to produce records without regulations explaining how to comply with FDA's new authority. Thus, in the interest of protecting the public health and eliminating any possible confusion about how to comply with FDA's expanded authority, FDA is dispensing with the need for prior notice and comment and is issuing this IFR.

Further, under 5 U.S.C. 553(d)(3) and § 10.40(d), we find good cause to make this IFR effective immediately. As stated previously in this document, to protect the public health it is necessary that we act quickly to make the regulation at issue consistent with the current statutory provisions in order to eliminate any possible confusion that may arise during the time that the regulation and statute are inconsistent. As discussed later in this document, FDA invites public comment on this IFR.

II. Analysis of Impacts

FDA has examined the impacts of this IFR under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts;

and equity). The Office of Management and Budget (OMB) has determined that this IFR is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the additional costs per entity of this IFR are negligible if any, the Agency also concludes that this IFR will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this IFR to result in any 1-year expenditure that would meet or exceed this amount.

In the 2003 proposed rule, FDA analyzed the economic impact of the proposed rule to require the establishment and maintenance of records and record availability requirements under the Bioterrorism Act (68 FR 25188). The Economic Impact Analysis of the 2004 final rule (69 FR 71562 at 71611) revised the analysis set forth in the 2003 proposed rule in response to comments on the proposed rule and to account for the changes between the proposed and final rules. The Economic Impact Analysis in this IFR explains and further revises the analysis set forth in the 2004 final rule by addressing the economic impact of the amendments made by section 101 of FSMA.

A. Need for Regulation

The need for this IFR arises from section 101 of FSMA which expands FDA's access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner. In addition, the FSMA amendment provides FDA additional access to records relating to articles of food for which FDA believes that there is a reasonable probability that the use of or exposure to the article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. This amendment will further help the Agency prevent potentially harmful food from reaching consumers and thereby improve the safety of the food supply in the United States. This IFR amends the record availability requirements in § 1.361 in accordance with the new records access authority in section 414(a) of the FD&C Act, which became effective immediately upon the enactment of FSMA.

B. Costs

FDA expects the costs related to this IFR to be negligible. According to the 2004 final rule analysis, the final rule covered more than 1 million entities, and this IFR covers those same entities.

Because, as a standard business practice, most firms were already capable of providing records access within 24 hours of a request, records access planning costs and records retention (which include storage and retrieval) costs were estimated to be zero in the 2004 final rule and were not reported in the total costs estimate.

As this IFR only affects FDA's authority to access already existing records, most records management procedures will not change. As stated in the 2004 final rule (69 FR 71562 at

71635), the estimated records access costs are based on the private costs of planning for a records access request. The costs to plan for a records access request are the same under this IFR as they were under the 2004 final rule, regardless of the number of records requested. FDA does not estimate the probability of a records access request. To the extent that FDA would have access to additional records that we previously could not access, the following potential costs could be incurred by both FDA and businesses:

1. Costs to FDA: Costs incurred by FDA could result from the additional time it would take to analyze records in order to complete an investigative visit. On average, records access times depend, in part, on how records are stored and maintained; average travel times, length of overnight stays required for completing an investigative visit; and average records analysis times. According to the 2004 final rule, the time required to analyze records depends on the quality of the records (69 FR 71562 at 71616). Potential costs to the Agency from this IFR in terms of additional time needed to analyze more records than under the 2004 final rule are expected to be small.

2. Costs to businesses: Costs incurred by businesses could result from an FDA access request requiring them to retrieve a larger number of records than they would have otherwise retrieved under the current authority. Similar to the costs of planning for a records access request, the 2004 final rule estimated records retrieval costs are also based on the private costs of retrieving records (69 FR 71562 at 71635). This IFR does not require firms to make any changes in records retention practices beyond the requirement in the 2004 final rule (69 FR 71562 at 71654), and thus the marginal cost is estimated to be negligible.

Since neither the FDA nor firms are able to predict the number of records requested to complete an investigation under the current authority or the new authority, additional costs to

retrieve any number of additional records are estimated to be the same under this IFR as they were under the 2004 final rule, regardless of the number of records requested.

FDA would use this new authority in a targeted fashion and it is unlikely that FDA would request all records from a suspect facility. The records FDA will access and copy will be focused on addressing the immediate needs of the inspection.

To the extent that FDA requests access to more records than it was previously allowed to access under similar circumstances, businesses may incur additional retrieval costs per record. However, the costs of retrieving one or more additional records from any number of records still remain part of the private costs for records retention which are determined by a firm's business plan. Thus, any potential costs to businesses from this IFR in terms of retrieving more records than under the 2004 final rule are also expected to be small.

C. Benefits

In the 2004 final rule analysis, FDA estimated the number of illnesses prevented (excluding those associated with food security) to be approximately 1,204 (69 FR 71562 at 71616). Averted illnesses in the 2004 final rule were attributed to having quicker access to records (24-hour time period) to initiate an investigation and also due to an increased ability to complete investigations that previously would have been prematurely terminated due to poor records quality (69 FR 71562 at 71614).

Similarly, the expected benefits from this IFR will be from minimizing consumer exposure to potentially dangerous foods. These benefits will be achieved by FDA having access to records beyond those relating only to the specifically suspect article of food. By expanding the current records access authority to include records relating to any other article of food that

FDA reasonably believes is likely to be affected in a similar manner, FDA can now access additional information that can enhance FDA's food safety efforts.

FDA has not quantified any additional benefits from this IFR, but because this IFR enhances food safety and security efforts, we reason that any benefits resulting from this IFR are likely to be in addition to benefits already estimated in the 2004 final rule.

III. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

FDA examined the economic implications of this IFR as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities.

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. In compliance with the Regulatory Flexibility Act this IFR will not have a significant impact on a substantial number of small businesses.

IV. Paperwork Reduction Act of 1995

This interim final rule contains information collection provisions that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or

action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361.

V. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this IFR in accordance with the principles set forth in Executive Order 13132. FDA has determined that the IFR does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency concludes that the IFR does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Comments

The requirements in this IFR will be in effect immediately upon publication in the Federal Register. FDA invites public comment on this IFR and will consider modifications to it based on comments made during the comment period when FDA issues the final rule. FDA intends to finalize this IFR 1 year from the close of the comment period.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in

brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Section 1.361 is revised to read as follows:

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, or when FDA believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other

information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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